UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS Hon. Patti B. Saris
THIS DOCUMENT RELATES TO: ALL ACTIONS	**REDACTED VERSION**

BAXTER INTERNATIONAL INC. AND BAXTER HEALTHCARE CORPORATION'S ("BAXTER") OPPOSITION TO PLAINTIFFS' MOTION FOR CLASS CERTIFICATION (AS TO THE TRACK TWO DEFENDANTS)

Dated: June 15, 2006

Respectfully submitted,

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Plaintiffs attempt to secure class certification in an egregiously haphazard manner: complaint allegations are not consistent with class certification pleadings; putative class representatives have neither purchased the drugs for which they are proposed nor made payments based upon AWP; and, in many instances, there is *no* evidence offered to prove alleged purchases. Plaintiffs' many failures are addressed in Defendants' Joint Opposition to Class Certification, individual defendant oppositions, and accompanying expert reports, all of which Baxter joins and incorporates herein by reference.

Plaintiffs' glaring errors are particularly pronounced when the Court focuses upon the allegations against Baxter. In short, plaintiffs "must establish that there is an individual class representative with standing to sue each defendant." *In re Pharm. Indus. AWP Litig*, 230 F.R.D. 61, 80 (D. Mass. Aug. 16, 2005). Plaintiffs have not offered a viable class representative as to Baxter for any of the three proposed classes, thereby precluding class certification.

I. No Class Can Be Certified As To Baxter International Inc.

One of the named Baxter defendants, Baxter International Inc. ("BII"), does not manufacture, market, or sell pharmaceuticals. Ex. A, Decl. Michael Bolton at ¶ 8. BII is merely a holding company that plays no role in the pricing, sales, distribution, or marketing of any Baxter drugs or therapies. *Id.* at ¶ 7. For this reason alone, the plaintiffs' allegations cannot apply and this Court cannot certify any class as to BII.

II. No Proposed Class 1 Representative Has Standing as to Baxter[1]

It is unclear which of the representatives is actually proffered as a representative for Baxter; the allegations in the FAMCC contradict the Class Certification Memoranda and proposed Orders. However, even the most liberal reading of plaintiffs' pleadings demonstrates

[1] On June 8, 2006, the Court allowed Plaintiffs to add Harold Bean as a proposed class representative and directed the parties to agree upon a discovery schedule as to Bean. Since discovery as to Bean has not yet occurred, Baxter reserves the right to supplement its opposition to Bean serving as a class representative.

that no typical Class 1 representative for Baxter is proposed. The record contains *no* evidence that any Class 1 representative was administered or paid for a Baxter drug. Further, even if plaintiffs had demonstrated purchases of Baxter drugs, all drugs at issue are multi-source drugs. The Joint Opposition shows why multi-source drugs cannot support class status or give rise to liability. *See* Track Two Def. Mem. Opp'n to Class Cert., Sec. II. E. 2. and III. Plaintiffs have failed to prove that any individual could be accepted as a class representative against Baxter and, as a result, the Court should refuse to certify any Baxter class. For the Court's convenience, the following chart (1) summarizes the putative named plaintiffs and the drugs/therapies at issue and (2) demonstrates the fatal inadequacies of plaintiffs' proof:

	Proposed Class Rep. Against Baxter	**Multi-Source Drug**	**Plaintiff Testimony of use of specific Baxter Drug**	**Evidence of Baxter Drug Purchase**	**Drug Reimbursement Based in Whole or Part on AWP**
Susan Aaronson [redacted][2] [redacted] [redacted]	No[3]	Yes[4]	No[5]	No Records provided	No[6]
Robert Howe [redacted]	Unable to Determine[7]	Yes[8]	No[9]	No[10]	No[11]

[2] Baxter produces a branded form of [redacted], called [redacted]

[3] Pl. Class Cert. Mem. at 3; Pl. Proposed Order at 3.

[4] Ex. B, 2004 *Red Book* at 186-87 ([redacted], 376-77 ([redacted], 551-52 ([redacted]); Ex. C, 2005 *Red Book* at 416-17 ([redacted]), 604-06 ([redacted]).

[5] Ex. D, Aaronson Tr. at 75:4-7; 110:16-20.

[6] *Id.* at 75:13-17; 25:9-26:10; 27:8-10; 28:20-29:10; 52:9-11.

[7] *See* Pl. Class Cert. Mem. at 2; Pl. Proposed Order at 2; Pl. Opp'n to Mot. to Strike at 3; Pl. Class Cert. Mem. at 2

[8] Young Report, Ex. 3-d.

	Proposed Class Rep. Against Baxter	Multi-Source Drug	Plaintiff Testimony of use of specific Baxter Drug	Evidence of Baxter Drug Purchase	Drug Reimbursement Based in Whole or Part on AWP
Roger Clark [redacted][12] [redacted] [redacted]	Yes	Yes[13]	No[14]	No[15]	No[16]
Larry Young [redacted] [redacted][17]	No[18]	Yes[19]	No[20]	No[21]	No[22]

[9] Ex. E, Howe Tr. at 120:21-122:1; *see also* Young Report, Ex. 7 at ¶¶ 19, 20.

[10] Ex. E, Howe Tr. at 151:8-10; *see also* Young Report, Ex. 7 at ¶¶ 19, 20.

[11] *Id.*

[12] Plaintiffs also allege that Clark was given Baxter's [redacted]; but, based upon prior agreement, plaintiffs have agreed not to pursue any Subject Drugs—including [redacted]—manufactured by Baxter's Anesthesia and Critical Care ("ACC") division. *See* Baxter's March 1, 2006 Motion to Extend Discovery and Amend CMO 23, fn. 3. The ACC Subject Drugs are: Aggrastat, Ativan, Brevibloc, Cisplatin, Doxorubicin, and Vancocin.

[13] Young Report, Ex. 3-c; Ex. F, 2001 *Red Book* at 508-10 ([redacted]); Ex. G, 2002 *Red Book* at 300-03 [redacted], 534-35 [redacted]; Ex. C, 2005 *Red Book* at 338-42 ([redacted]); Ex. H, Clark Tr. at 80:20-81:1.

[14] Young Report, Ex. 3-c; Ex. H, Clark Tr. at 73:13-17 ([redacted]); 80:20-81:1 ([redacted]).

[15] Young Report, Ex. 3-c; Ex. H, Clark Tr. at 74:11-13 ([redacted]; 83:14-16 ([redacted]; 85:1-8 ([redacted]).

[16] Young Report, Ex. 3-c; Ex. H, Clark Tr. at 67:4-70:1 ([redacted]); 74:4-6 ([redacted]; 83:6-13 [redacted]).

[17] Baxter produces a branded form of [redacted] called [redacted] which is an [redacted] drug; [redacted]

[18] Pl. Class Cert. Mem. at 2; Pl. Proposed Order at 2.

[19] Ex. B, 2004 *Red Book* at 376-77; *see also* Young Report, Ex. 4-B.

[20] Ex. I, Young Tr. at 75:6-76:5; 64:1-13.

[21] *Id.*

[22] Ex. I, Young Tr. at 64:1-13.

III. Class 1 Cannot Be Certified Against Baxter For Drugs Or Therapies That Were Not Purchased By Any Proposed Class Representative

In addition to the drugs described above, Revised Appendix A to the FAMCC identifies several additional Baxter Subject Drugs: Bebulin, Claforan, Gammagard, Gentran, Iveegam, Osmitrol, Recombinate, and Travasol.[23] Plaintiffs have failed to identify any proposed Class 1 representative for these drugs. Plaintiffs have similarly failed to prove any purchases or payments for these drugs based upon AWP. Without a Class 1 representative who purchased these drugs, plaintiffs cannot meet Rule 23 requirements and the Court cannot certify a Class 1 representative relating to these drugs. *E. Tex. Motor Freight Sys., Inc. v. Rodriguez*, 431 U.S. 395, 403 (1977) (citation omitted) ("a class representative must be part of the class and 'possess the same interest and suffer the same injury' as class members").

IV. No Proposed Class 2 Representative Has Standing as to Baxter

The sole Class 2 plaintiff, Sheet Metal Workers National Health Fund ("Sheet Metal Fund"), alleges the purchase of only **one** Baxter drug, heparin sodium, in 2004.[24] *See* Affidavit of Glenn Randle, Ex. 2. Heparin sodium is a multi-source drug, and the evidence does not establish that the heparin sodium, for which Sheet Metal Fund paid, was manufactured by Baxter. Young Report, Ex. 4-B[25]; Ex. B, 2004 *Red Book* at 376-77. Further, the evidence establishes that the heparin was reimbursed under the hospital OPPS payment scheme and, thus,

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[23] The ACC drugs described in fn. 12 have been omitted here.

[24] The Randle Affidavit makes reference to other Baxter drugs—Brevibloc, Cisplatin, Doxorubicin, Vancocin—all of which are ACC drugs subject to the agreement referenced above in footnote 12. Transactions related to two drugs, Brevibloc and Travasol, were in fact billed under the J-Code for "unclassified drugs." Young Report, Ex. 4-B, note 2. As Young concludes, these cannot in any sense be argued to be Subject Drugs as it is not even possible to determine the identity of the drugs. *Id.* As with heparin sodium—and notwithstanding the assertions of single source in the Randle Affidavit (¶ 5 and Ex. 2)—all of these drugs are multi-source and there is no proof of the source of supply associated with the J-Code. Young Report, Ex. 4-B.

[25] In fact, Sheet Metal Fund appears to concede that it does not know the source(s) of its multi-source drugs. *See* Randle Affidavit at ¶ 6 ("[the multi-source drugs] *may* have been manufactured and sold by the following defendants . . . .") (emphasis added).

was not reimbursed on the basis of AWP. Young Report, Ex. 4-B; *see also* Young Report at ¶¶ 53-55. Having alleged no reimbursements for any Baxter drug, Sheet Metal Fund cannot claim any injury traceable to Baxter and lacks standing as a class representative. *See Allen v. Wright*, 468 U.S. 737, 751 (1984) ("plaintiff must allege personal injury fairly traceable to the defendant's allegedly unlawful conduct" in order to establish Article III standing).

V. No Proposed Class 3 Representative Has Standing as to Baxter

The sole Class 3 plaintiff, Pipefitters Local 537 Trust Funds ("Pipefitters"), fails to establish that it purchased **any** Baxter Subject drug. Pipefitters alleges in a conclusory chart lacking any factual foundation that it purchased several multi-source Baxter Subject Drugs under various J (or HCPCS) Codes.[26] *See* Declaration of Charles Hannaford ("Hannaford Decl."). Under the first codes (J1561, J1562, J1563), the drug allegedly purchased appears to be immune globulin, but it is not clear which company manufactured the reimbursed drug. *Id.* The same is true with respect to drugs purchased under the J Codes J1642 (heparin), J7030, J7040, and J7050 (sodium chloride), J7194 (Bebulin), and J3490[27]. Hannaford Decl., Ex. 1. There are multiple manufacturers whose drugs are reimbursed under these J codes[28] and Pipefitters has presented no evidence that the drugs in question were manufactured by Baxter. *See* Young Report at ¶ ¶ 113-116. Having established no actual reimbursements for any Baxter drug, Pipefitters cannot claim any injury traceable to Baxter. *See Allen*, 468 U.S. at 751.

Even if the Court were to find that the mere *possibility* that a Baxter drug was administered/paid for was sufficient to establish standing, the investigation required to establish which members of the class might have reimbursed for a particular defendants' drugs would

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[26] Again, Baxter is not addressing herein those ACC drugs subject to the agreement described in fn. 12. These include Vancocin (also known as vancomycin) (J3370) and Brevibloc (J3490).

[27] Per plaintiffs, this J Code includes Travasol, though in actuality it is a J-Code for an "unclassified drug." *See* Young Report, Ex. 6, n. 15.

[28] Young Report, Ex. 6

necessitate an individualized inquiry not appropriate in a class action, Young Report at ¶ 117, and such an inquiry likely would not be fruitful. *Id.* at ¶¶ 12, 13, 36, 117.

VI. Multiple Source Drugs Cannot Be Included In This Class Action

All of the Baxter drugs and therapies included as Subject Drugs in the FAMCC are multiple source drugs. Under Medicare Part B, reimbursement for multiple source drugs is a function not of any one company's AWP, but the lower of the median AWP for all drugs in a therapeutic class, or "J-Code," or lowest AWP for the brand name drug or biological. *See* 42 C.F.R. § 405.517. In the private payor arena, multiple source drug and therapies are also typically reimbursed based upon J-Code, or some other non-AWP based reimbursement formula. Young Report at ¶¶ 10, 41. One manufacturer, thus, cannot gain competitive advantage by raising its AWP. Young Report at ¶¶ 12, 13, 39, 69, 70. Absent a link to AWP based reimbursement, plaintiffs cannot show a personal injury traceable to Baxter and, thus, lack standing to pursue claims. *See Allen*, 468 U.S. at 751.

VII. Liability Against Baxter Cannot Be Established on the Basis of Class-wide Proof And Common Questions Of Law And Fact Do Not Predominate

To demonstrate that a particular element or defense of a claim presents a common issue, plaintiffs must establish that the particular element can be proven for all class members without resort to individual proof that is specific to any one of them. *Thorn v. Jefferson Pilot Life Ins. Co.*, 445 F.3d 311, 322-23 (4th Cir. 2006) ("Our cases permit no exception to the rule that the plaintiff bears the burden of showing compliance with Rule 23."). Because of the complexity of the above issues, plaintiffs cannot establish that "a class action is *superior* to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(3) (emphasis added). The array of Baxter drugs at issue and the manner in which they are marketed further complicate any class analysis and demonstrates that individuals' issues dominate.

Baxter Healthcare Corporation consists of multiple businesses. Those at issue here are Medication Delivery, which manufactures intravenous and irrigation solutions, and BioScience, which produces hemophilia, immune globulin intravenous ("IVIG") therapies, and other biologics. Not only do these divisions manufacture and produce completely unrelated drugs and therapies, they also sell to different customers. Medication Delivery drugs are sold primarily to hospitals as bundled offerings, usually coupled with delivery systems (hardware, pumps, etc.) used to infuse the drugs. Medication Delivery's intravenous drugs are essentially commodity items. In contrast, BioScience therapies, particularly the hemophilia therapies, are typically sold to highly specialized treatment centers and home healthcare providers. BioScience's hemophilia and IVIG drugs are highly specialized and purchasing decisions for these drugs are made on the basis of safety and necessity.

Class treatment is not appropriate as to plaintiffs' claims against Baxter because plaintiffs cannot offer class-wide proof of its claims, and common questions of law and fact do not predominate. Plaintiffs must offer individualized proof regarding each market participant's knowledge of the meaning of AWP, causation, and damages it suffered as a result of the alleged AWP scheme. This inquiry is dependent upon a detailed analysis of the individual relationships between the payor and the provider to determine the actual effect of AWP on reimbursement rates. When a particular fact is only "typically" true among class members—or is even true for most class members most of the time—the matter is not susceptible to common proof and presents an individual issue. *Thorn*, 445 F.3d at 322-23; *see also General Motors v. Garza*, 179 S.W. 3d 76, 81 (Tex. App. 2005) ("Inescapably individual differences cannot be concealed in a throng. The procedural differences of a class action eliminates the necessity of adducing the same evidence over and over against in a multitude of individual actions. It does not lessen the quality of evidence required in an individual action or relax burdens of proof."). Based upon the

pricing and marketing differences between Medication Delivery's ubiquitous intravenous solutions and BioScience's highly-specialized hemophilia and immune globulin therapies, evidence as to one type of drug or therapy cannot be utilized as evidence as to other drugs, therapies, or biologics. The drugs and therapies compete in very different markets and under very different circumstances and are priced and reimbursed in diverse ways. Because of these particularities, the matter is not susceptible to common proof and presents a multitude of individual issues.

Conclusion

For the foregoing reasons, as well as the reasons contained in the Joint Opposition to Class Certification and other individual defendant oppositions, plaintiffs' motion for class certification as to Baxter should be denied.

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of June, 2006, a true and correct copy of the foregoing document was served upon all counsel of record by causing same to be posted electronically via Lexis File & Serve.

/s/ Shamir Patel
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